Universitat de Girona
Facultat de Medicina

CARDIAC REHABILITATION IMPROVES THE QUALITY OF LIFE OF PATIENTS WITH CORONARY HEART DISEASE OR HEART FAILURE

A RANDOMIZED CONTROLLED TRIAL

Final degree project

Berta Campos Mercadé
Tutor: Carlos Azuaje Tovar
November 2016

HOSPITAL DE CERDANYA / HÔPITAL DE CERDAGNE
AECT - Agrupació Europea de Cooperació Territorial / GECT - Groupement Européen de Coopération Territoriale

Servei de Medicina Interna
HOSPITAL DE CERDANYA

I warmly thank all the team of *Hospital de Cerdanya*,
for having so kindly accepted me as one of their own.

Thank you, Carlos, for your patience.

Thanks to everyone who helped
and contributed to this project.

ALWAYS LAUGH WHEN YOU CAN,
IT IS CHEAP MEDICINE.

Table of Contents

1. ABBREVIATIONS

ACC/AHA	American College of Cardiology/America Heart Association
ACD	Acute coronary disease
CHD	Coronary heart disease
CR	Cardiac rehabilitation
CRP	Cardiac rehabilitation program
CV	Cardiovascular
CVD	Cardiovascular disease
CVR	Cardiovascular risk
ESC	European Society of Cardiology
HF	Heart failure
HRQoL	Health related quality of life
LDL-C	Low-density lipoprotein cholesterol
MI	Myocardial infarction
NSTEMI	Non ST-segment elevation myocardial infarction
PE	Physical exercise
QoL	Quality of life
SEC	Sociedad Española de Cardiología
STEMI	ST-segment elevation myocardial infarction
WHO	World Health Organization

2. ABSTRACT

CARDIAC REHABILITATION IMPROVES THE QUALITY OF LIFE OF PATIENTS WITH CORONARY HEART DISEASE OR HEART FAILURE

Background: The aim of cardiac rehabilitation is to restore the patient's physical, psychological, economical and social stability. The most prominent results of cardiac rehabilitation have been: the improvement of patient's quality of life, the reduction of mortality, morbidity and of the risk of future hospital readmission. Cardiac rehabilitation is a combination of physical exercises alongside with educational and psychological support. In evaluating rehabilitation strategies, the quality of life measurements have been indispensable methods for determining changes in the psychological and social well-being of the patient.

Objective: The aim of this project is to contribute towards the establishment of cardiac rehabilitation programs by supplementing the already existing evidence of its effectiveness. This, we intend to achieve by providing a report on the subject that better reflects the real world practice including the recruitment of older and higher risk patients.

Design: We will conduct a *randomized controlled trial* including 496 patients who will be assigned to either participate in a cardiac rehabilitation program or receive the standard care currently provided by our public health system. This study will be conducted over a period of four years. During this time we will assess and compare the changes in the health related quality of life of all the participants.

Setting: This study protocol will take place in *Puigcerdà*, *La Cerdanya*.

Participants: The participants will be adult patients with coronary heart disease or heart failure who do not show contraindication for physical exercise. We will invite the patients of *Hospital de Cerdanya*, who meet the criteria to participate in the trial from December 2016 to January 2019.

Key words: Cardiac rehabilitation. Coronary heart disease. Heart failure. Quality of life. SF-36. Secondary prevention.

3. DESCRIPTION OF THE CONDITIONS

In this study we will focus on patients who suffer from coronary heart disease and/or heart failure. Here we are exposing what is considered relevant to contextualize these conditions.

3.1. CORONARY HEART DISEASE (ISCHEMIC HEART DISEASE)

3.1.1. Myocardial ischemia

Ischemia is caused by a mismatch between blood demand and supply; it is a condition of oxygen deprivation and incorrect elimination of waste metabolites (1).

The heart receives its own blood supply through the coronary arteries. Myocardial ischemia then occurs when there is a reduction of the blood flow that nourishes the heart muscle. In most cases, this is a result of a partial or complete blockage of one or more of the coronary arteries.

The causes of myocardial ischemia are many. However, among all of them, the most common one and the main underlying process that result in cardiovascular diseases is atherosclerosis (2). There are other less prevalent causes like coronary artery spasm, small blood vessels disease or arteritis among others (3).

3.1.2. Physiopathology of atherosclerosis

Atherosclerosis is a complex pathological process that takes place in the walls of the blood vessels and it develops over many years. It is an inflammatory process that affects medium and large sized vessels throughout the whole vascular system.

The risk factors of developing atherosclerosis and thus all cardiovascular diseases, which we will discuss in detail in the following section, are:

- Behavioral risk factors: Smoking tobacco, physical inactivity, unhealthy diet, harmful consumption of alcohol,
- Metabolic risk factors: Hypertension, diabetes, hypercholesterolemia, overweight

and obesity,
- Demographic risk factors: Old age, male gender, poverty and low educational status,
- Genetic predisposition,
- And others such as psychological conditions.

There is strong scientific evidence that behavioral and metabolic risk factors play a key role in the ethology of atherosclerosis (2).

The endothelium becomes permeable to inflammatory cells when it is exposed to high levels of LDL cholesterol and other substances such as free radicals. In the subendothelium the inflammatory cells become fatty cells and create fatty streaks. At some point these cells will begin to die, thus creating a necrotic core covered by a layer of collagen and smooth muscle. These lesions are called atheromatous plaques and keep growing as cells and fat accumulate in them. The plaque bulges into the lumen narrowing the blood vessel.

As the process continues, the fibrous layer becomes thinner and can get fissured. After either a plaque rupture or an endothelial erosion, the subendothelium is exposed to the circulating blood, which leads to platelet adhesion, followed by platelet activation and aggregation, and the subsequent formation of a thrombus.

Although plaque rupture may result in acute coronary disease (ACD), in 99% of cases it is clinically silent. The rate of progression of atherosclerotic lesions is variable, nonlinear, and unpredictable (4).

(2,3,5)

3.1.3. Coronary heart disease prevention

The prevention of the coronary heart diseases (CHD) is included in the prevention of all cardiovascular diseases (CVD). The last one is defined by the European Society of Cardiology (ESC) as: a coordinated set of actions, at the population level or targeted at an individual, that are aimed at eliminating or minimizing the impact of CVDs and their related disabilities (6).

The majority of CHD and CVD are induced by certain risk factors (CVRF). Most CVRF can be controlled, treated or modified, but some cannot. Nevertheless all of them should be taken into account. The reason being that often these risk factors coexist in the same person and act synergistically increasing the individual's total risk of developing a CVD.

The most recent guidelines recommend the assessment of the total cardiovascular risk (CVR) since prevention of CVD in an individual should be adapted accordingly: *The higher the risk, the more intense the action should be* (6,7) .

To this end, there are CVR stratification tables to help establishing the criteria of when to start the treatment. These tables predict the risk of developing a cardiovascular event in 10 years time. The most used risk equations are Framingham and SCORE. The group REGICOR adapted the Framingham risk estimation to the characteristics of the Spanish population (and the study VERIFICA demonstrated it), so REGICOR tables are the ones to be used in our area (7,8).

Individuals with the following conditions, listed below, are at *high* or *very high* total CVR. Thus, for them there is no need for risk estimation models, since they all automatically meet the criteria for active treatment. These are:

- Documented cardiovascular disease (all patients with coronary heart disease fall into this category),
- Diabetes (type 1 or type 2),
- Very high levels of individual risk factors,
- Chronic kidney disease.

Since most of our patients fall in the category of *high* or *very high CV risk*, we are here describing the treatment objectives for this particular group of patients.

There are three levels of prevention. When the focus is on reducing the disease progression, as it is the case for our patients, it is called *secondary prevention*. So all measures exposed here are secondary prevention measures (for patients who already present the disease). Cardiac rehabilitation is also considered to be a secondary prevention intervention (although before it was said to be *tertiary prevention*).

Modifiable risk factors

Hypertension: Hypertension is defined by the ESC as a repeatedly elevated systolic pressure of 140mmHg or higher and/or a diastolic pressure of 90mmHg or higher (6,9). For secondary prevention the recommendation is to keep blood pressure values under 140/90mmHg except for patients with diabetes mellitus (DM) whose goals are 140/85mmHg (this matter is in constant revision and recommendations keep changing, we are following the last ESC publications) (9).

Smoking tobacco: Smoking tobacco is the totally avoidable risk factor of CVD. The recommendation is not to be exposed to tobacco in any form.

Raised blood glucose (Diabetes Mellitus): Raised blood glucose is defined as having a fasting plasma glucose value of 7.0 mmol/l (126 mg/dl) or higher. The risk of cardiovascular events is, in average, two to threefold higher in people with diabetes. For secondary prevention the target is a glycated hemoglobin (HbA1c) of 6.5%-7.5% (48-58mmol/mol) (6).

Physical inactivity: Physical inactivity is the fourth leading risk factor for mortality (2,5). The treatment goal for CVD prevention on physical exercise (PE) is 2.5-5 hours of moderate activity per week or 30-60 minutes most days (6). PE is fundamental in energy balance and weight control; it improves endothelial function which enhances vasodilatation in the blood vessels; it contributes to weight loss, glycemic control and improves blood pressure, lipid profile and insulin sensitivity. Thus, PE is beneficial through all these effects on intermediate risk factors for CVD.

Unhealthy diet: Adequate consumption of fruits and vegetables, reduction of trans-fats and replacement of saturated fats with unsaturated fats reduces the risk of CVD. A healthy diet contributes to a healthy body weight, a desirable lipid profile and a desirable blood pressure (2,5).

Overweight and obesity: Obesity is a cardiovascular risk factor closely related to diet and energy expenditure (PE). It directly affects risk factors such as raised blood pressure, glucose intolerance, type II diabetes and dyslipidemia. The goal is thus for the patient to maintain a BMI (body mass index) of 20-25 kg/m2 (2,5) and waist circumference of less than 94cm in men and less than 80cm in women (6).

Cholesterol/lipids (Dyslipidemia): The cholesterol profile includes LDL cholesterol (low density lipoprotein is deposited in the walls of arteries and initiates the process of atherosclerosis), HDL (high density lipoprotein removes LDL cholesterol out of the artery's walls and protects against vascular disease) and triglycerides.

Current guidelines on this subject strongly emphasize the importance of LDL-C lowering to prevent CVD. It is also confirmed that there is a direct correlation: *the greater the LDL-C reduction, the greater the reduction on CVR*. And there are no differences in the relative reduction between men and women, between younger and older age or between those with and without DM (6):

- For patients at a *very high CV risk* the goal of LDL-C is less than 70 mg/dL, or a reduction of at least 50% if the baseline is between 70 and 135 mg/dL.
- For patients at a *high CV risk* the goal of LDL-C is less than 100 mg/dL or a reduction of at least 50% if the baseline is between 100 and 200 mg/dL.
- And, among the remaining patients on LDL-C lowering treatment the goal of less than 115 mg/dL should be considered.

Non-modifiable risk factors

In addition, some CVRF, which increase the patient's total CVR, cannot be changed. It is recommended that people in these risk categories should receive more frequent check-ups (2,5). These are as follows:

Age: CVD become increasingly common with advancing age.

Male gender: A man is at greater risk of a heart disease than a pre-menopausal woman. Once past the menopause the woman's risk is similar to the man's.

Family history and genetics: If a first-degree blood relative had a coronary heart disease or a stroke before the age of 55 for a male relative or 65 for a female relative the risk increases.

3.1.4. Clinical classification of the coronary heart disease

A coronary heart disease (CHD) is the clinical result of myocardial ischemia and it includes: angina, unstable angina and myocardial infarction (with or without ST segment elevation) as the common clinical presentation. It can also manifest as a subclinical change (unnoticed), different degrees of heart failure, arrhythmias or sudden death (1,3). The first classification of a CHD is whether it is acute or stable.

3.1.4.1. Stable coronary disease: general definition and prognosis.

Stable CHD is characterized by episodes of reversible myocardial ischemia, which must be inducible and reproducible (by exercise, emotion or other stress), however, it can occur spontaneously. Stable CHD episodes are commonly associated with transient chest discomfort, commonly referred as *angina*.

Mortality of patients with stable coronary disease is arround 2% per year, although individual's prognosis vary considerably depending on the concrete characteristics of the patient. For example: very high risk patients (with peripheral arterial disease, previous myocardial infarction or diabetes) have an estimated mortality of 3.8% per year; whereas low-risk patients (with non-obstructive plaques within the coronary arteries) have an estimated annual mortality rate of 0.63% (1).

The ways of improving the prognosis of stable coronary disease are: correction of cardiovascular risk factors through life style changes, coronary thrombosis prevention with antiplatelet drugs, beta blockers and angiotensin-converting enzyme inhibitors therapy for patients with previous infarction, and coronary revascularization for high-risk patients.

3.1.4.2. Acute coronary disease: general definition and prognosis

Acute coronary disease (ACD) refers to any group of clinical symptoms related to acute myocardial ischemia. It happens as a result of a sudden stop of the artery blood flow to the myocardia. Atherosclerosis is the cause of more than 90% of them.

ACD includes unstable angina, non ST-segment elevation myocardial infarction (NSTEMI), and ST-segment elevation myocardial infarction (STEMI). All three of them: have similar pathophysiology and clinical presentations, however they differ in severity.

Unstable angina needs one or more of the next criteria as well as the absence of an elevation of a cardiac troponin in the blood stream:

- Rest angina (usually lasting >20 minutes),
- New-onset severe angina (<2 months), and/or
- A crescendo pattern of occurrence (increasing in intensity, duration, frequency, or any combination of them).

A *myocardial infarction* (MI) is diagnosed when the ischemia is as severe as to cause enough myocardial damage that results in a dynamic elevation of a cardiac troponin. The elevation must be above the 99th percentile of a healthy person(10).

At this point a MI has been diagnosed, and next we need the resting 12-lead ECG to distinguish between NSTEMI from STEMI. In the case of a NSTEMI the ECG will either appear normal or with abnormalities such as ST depression, transient ST elevation or T-wave changes. And the finding of a persistent ST-segment elevation indicates STEMI (and this mandates immediate reperfusion).

The Global registry of acute coronary events (GRACE) is an international observational database of outcomes for patients with an acute coronary syndrome. If we apply this scale we can estimate the risk of mortality in six months time. This scale includes the following factors: age, heart rate, systolic arterial pressure, class of heart failure, creatinine level, ST-segment deviation, cardiac arrest at admission and elevated troponin (or other necrosis biomarker) (11).

3.1.5. Epidemiology of coronary heart disease

We want to present the impact of this group of diseases on the population. The best measures to do so are incidence and prevalence. *Incidence* is the number of new cases during a specific period of time and *prevalence* is the number of existing cases within the population.

Estimation of the epidemiology of all CHD is complex since it includes many different diagnosis and the estimations vary greatly depending on the country and age group. Since

this is the case, we have gathered data from different sources with the aim of getting a general overview of the magnitude of the problem.

Incidence

First we are presenting rates of hospital discharge from CHD in Europe and in Spain in 2008. From the *Health for all Database* (WHO Europe) we obtained the rates of hospital discharge from CHD which gives us an idea of the incidence of the disease. In 2008 in Europe a sum of 631 hospital discharges from a coronary heart event per 100.000 habitants were registered. In Spain it was a total of 320 hospital discharges from a coronary heart event per 100.000 habitants (12).

Regarding the incidence of uncomplicated angina the available data suggests an annual incidence of 1.0% among the male western populations between the age of 45–65 years, and a slightly higher incidence among women. It is also noteworthy that there is a steep increase after the age of 65 for both genders, the population between the age of 75–84 years reach almost 4% of incidence of angina (1).

Since from all coronary heart diseases, acute coronary diseases are the leading cause of morbidity and mortality; therefore we examined ACD's incidence data relevant to all CHD. In the study called *Estimation of the Number of Cases and Trends From 2005 to 2049* from 2005 it was predicted that in Spain in 2013 there would be 115,752 cases of ACD (74,078 in men and 41,674 in women) and 28-day mortality was projected to be 39,086 of the total (33.8%) (13).

Next, we will we present two studies focusing on Catalunya's population: one of them was run in Girona and the other in Manresa. These represent the closest studies to the population we will examine and thus hopefully the ones that can describe it the best).

The Girona Heart Registry (REGICOR) registered the incidence of CHDs from 2000 to 2009 in the population of Girona between the ages 35-74 years as 409.6 per 100,000 men and 152.8 per 100,000 women (14).

In a cohort of Manresa the incidence of CHD was 499,80 per 100,000 habitants. The reason for it to be so unusually high is that it was a cohort of men workers of chemical industries with very high rates of smokers (15).

Prevalence

Regarding the prevalence of CHD we will focus on the prevalence of angina since this one is not a good epidemiological measure to evaluate acute events like ACD.

The prevalence of proven angina definitely increases with age as well. In Spain between the ages of 40-50 is less than 1% while it increases drastically in patients between the ages of 70-80 getting to 7.1% (16).

In conclusion

CHD is of major importance to the health interest. It is the cause of the majority of deaths in most of the age groups, although the mortality from CHD has progressively decreased in the last twenty years (which is due to both improvement of the treatment for the acute phase as well as preventive measures) (17).

Even though CHDs' incidence continues to decrease in developed countries, immigration and the progressive populations' aging suggest that the total number of coronary events and, consequently, the prevalence of CHD will not decrease and may even increase in the near future. Meanwhile, the globalization of the western diet and the increasingly sedentary behavior will robustly influence the progressive increase of the incidence of CHD in developing countries (18).

3.2. HEART FAILURE

3.2.1. Definition of Heart Failure

Heart failure (HF) is a clinical syndrome characterized by typical symptoms (like breathlessness, ankle swelling and fatigue) that may be accompanied by signs (like elevated jugular venous pressure, pulmonary crackles and peripheral oedema).

HF can be caused by structural and/or functional abnormalities and it can result in a reduced cardiac output and/ or elevated intracardiac pressures while the patient is at rest or under stress (exercise, emotional, or another systemic disease) (16).

3.2.2. Clinical presentation of Heart Failure

HF is a clinical syndrome characterized by:

Typical symptoms: Dyspnea (is the subjective feeling of not being able to breath well and it is the most frequent symptom of HF), orthopnea (is dyspnea while in decubitus position that improves when standing up, it happens because of the increased venous return), nocturnal cough, reduced exercise tolerance, fatigue, wheeze, confusion and even delirium in elderly (20).

T*ypical signs*: Peripheral edema, ascites, crepitation or wheeze, tachycardia, third heart sound, displaced apex beat, elevated jugular venous pressure, hepatomegaly, cachexia and muscle wasting (20).

The current definition of HF includes only stages at which clinical symptoms are apparent, but before this takes place patients can present asymptomatic abnormalities which may result in future HF (for example, systolic or diastolic left ventricular dysfunction). The recognition of these precursors is important since starting the treatment already at this early stage may reduce mortality in these patients (19).

3.2.3. Clinical classifications of Heart Failure

Functional classification of Heart Failure

The New York Heart Association (NYHA) established a classification according to the severity of symptoms. It classifies patients in four categories based on how much they are limited during physical activity.

Class I: No limitation of physical activity. Ordinary physical activity does not cause fatigue, palpitation or dyspnea (shortness of breath).

Class II: Slight limitation of physical activity. Comfortable at rest but ordinary physical activity results in fatigue, palpitation and/or dyspnea (getting dressed, for example).

Class III: Marked limitation of physical activity. Comfortable at rest but less than ordinary activity causes fatigue, palpitation, or dyspnea.

Class IV: Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken discomfort increases.

Classification of Heart Failure according to ejection fraction

On the other side the ESC published the last guidelines on HF in 2016 and again described the classification according to the ejection fraction of the left ventricle (LVEF). This is usually measured using echocardiography, a radionuclide technique or cardiac magnetic resonance (3,19).

The differentiation of patients with HF based on LVEF is important due to different underlying etiologies, demographics, co-morbidities and response to therapies. And it is only in patients with reduced ejection fraction (HFrEF) that therapies have been shown to reduce both morbidity and mortality.

Classification of HF according to ejection fraction:

Heart failure with reduced ejection fraction (HFrEF): symptoms +/- signs and LVEF less than 40%.

Heart failure with mid-range ejection fraction (HFmrEF): symptoms +/- signs and

LVEF 40-49%. Plus elevated levels of natriuretic peptides and at least one of the following: relevant structural heart disease or diastolic dysfunction.

Heart failure with preserved ejection fraction (HFpEF): symptoms +/- signs and LVEF more than 50%. Plus elevated levels of natriuretic peptides and at least one of the following: relevant structural heart disease or diastolic dysfunction.

3.2.4. Causes of Heart Failure

Demonstration of an underlying cause is central to the diagnosis and treatment of HF (19). Normally it is a myocardial abnormality that causes systolic or diastolic ventricular dysfunction, however there are many relevant causes, such as, abnormalities of the valves (insufficiency or stenosis), abnormalities of the pericardium or the endocardium, arrhythmias, conduction problems or congenital heart defects.

3.2.5. Epidemiology of Heart Failure

The prevalence of HF depends on the definition applied and it varies depending on the age group and the level of development of the country. The prevalence of HF is about 1 to 2% in the western world. And it increases with age, thus it is around 10% among people older than 70 years (20).

The incidence of HF in the western world approaches to 5-10 per 1000 persons per year (19).

Even among patients with HF most deaths occur due to cardiovascular causes (mainly due to sudden death and HF worsening). The most recent European data said that 12-months mortality for patients with HF was 17% for hospitalized and 7% for ambulatory patients (21).

4. DESCRIPTION OF THE INTERVENTION

4.1. What is cardiac rehabilitation?

Cardiac rehabilitation (CR) has many definitions, a very broad one could be: The coordinated sum of activities required to influence favorably the underlying cause of certain cardiac diseases; as well as to provide the best possible physical, mental and social conditions so the patients may preserve optimal functioning and slow or reverse the progression of the disease by improving their health behavior (22).

In 2016 the ESC stated that the only non-pharmacological, non-device and non-surgical intervention that works in the treatment of CHD as well as HF is the implementation of care in a multidisciplinary framework, with monitoring and exercise training; which are the main points of CR.

From the last ESC guidelines:

- Participation in a cardiac rehabilitation program (CRP) for patients hospitalized for an acute coronary event or revascularization, and for patients with HF, is recommended to improve patient outcomes. Class of recommendation I, level of evidence A (6).
- A multidisciplinary care management program is recommended in patients with HF to reduce the risk of hospitalization and mortality. Class of recommendation I, level of evidence A (19).

(Classes of recommendation and levels of evidence in *Annex I*)

4.2. Details of a Cardiac Rehabilitation Program

Both CHD and HF are chronic conditions and patients are at high risk for new cardiac events and premature death (14,21). CR takes part here, as a long-term management and secondary prevention for this large group of patients.

One of the most relevant features of CR is to inspire a change of these patients' lifestyle, including: smoking cessation, a tight blood pressure control, a healthy diet, an adequate

body weight and regular physical exercise. The implementation of life-style changes are not easy and take long, in this regard, it is proven that these expected changes should already be mentioned and initiated before patient's discharge (24). At this point a close collaboration between cardiologist, general practitioner, nurse, dieticians and psychotherapists is critically important.

A CRP is compounded by three main interventions: 1. Physical exercising, 2. Psychological intervention, and 3. Patient's education.

4.2.1. Physical exercising

A large meta-analysis on regular physical exercising (PE) as part of a CRP was associated to a reduction of 26% in cardiac mortality (25). Besides this, PE has other beneficial effects such as a better cardiorespiratory fitness and a general increase of the patient's well being (at least during the training period and even in elderly patients) (23).

The benefits from PE include (23,24): improved endothelial function, reduced thrombogenic risk (fibrinogen and platelet aggregation lowers and fibrinolysis increases), improved capillarity of coronary arteries, bigger diameter of coronary arteries, better collateral circulation, higher levels of oxygen in blood circulation, decreased inflammatory activity, decrease of dyspnea, higher vital capacity, better diaphragmatic movement and decrease in stress, depression and anxiety.

Aerobic exercise training should always be offered to patients with CHD or HF. But before that it is crucial that the patient undergoes a *cardiac stress test*, which evaluates both exercise capacity and exercise-associated risk.

A *cardiac stress test* will provide necessary information about:

- The intensity of the exercise: the heart frequency should be 75-80% of the patient's maximum (or before symptoms or electric variations if these manifest),
- The risk of arrhythmias,
- Inadequate responses to exercise.

Once the patient has undergone the cardiac stress test and there are no relevant irregularities, the recommendation of the ESC is *30-40 minutes of moderate intensity aerobic exercise at least five times per week* (13).

High-level resistance exercises could suddenly increase blood pressure without changes in cardiac frequency, so they should be avoided in patients suffering from atherosclerosis.

At this point it is also important to be aware of the contraindications of PE (24):

- *Absolute contraindications of physical exercising* are only two: advanced hypertrophic cardiomyopathy and thrombosed dissecting aortic aneurysm. Even in these cases, low levels of aerobic exercise could be recommended.
- *Temporal contraindications for physical exercising*: The coexistence of acute comorbidities (like badly controlled diabetes, pneumonia or thrombophlebitis) or decompensated cardiologic problems (unstable angina, threatening arrhythmias or pericarditis).

(23,24)

4.2.2. Psychological interventions

The incidence of emotional disorders after CHD or HF are very frequent, patients tend to be scared, have fear of death and feel depressed. Here, an early intervention may improve patients' quality of life significantly. A meta analysis of 37 studies by Dusseldorp concluded that the psychological intervention in CRP decreases participant's mortality in 34% and the risk of a second myocardial infraction in 29% (26).

The psychological support includes many interventions that will help the patient through their condition and contribute to their better rehabilitation.

Stress management can be very beneficial in this situation. Cognitive behavioral therapy focused on stress management, showed a 41% lower rate of fatal and non-fatal first recurrent cardiovascular disease events than the group control (27).

Other interventions in this context include helping the patient to take proper care of his/her health, improving their communication skills, and enhancing family and surroundings' engagement and support towards the patient's health.

4.2.3. Patient's education

It is important that health care professionals give advice on how to improve patient's health behavior and therefore their health condition.

As the most relevant aspect, special emphasis should be placed on the risk factors control: Hypertension, dyslipaemia, glucose blood control, overweight, diabetes, and smoking cessation.

Providing clear information about their own health condition is important for the patients to take responsibility and increase autonomy. Details about the drugs they got prescribed, how they operate in the body and why it is important to keep taking them likely increases the patient's compliance.

4.3. Cardiac rehabilitation programs

This kind of interventions are complex and need advanced organization and depend a lot on the available means, so every country must adapt the program to their needs and possibilities.

There are two main kind of CRP: Supervised and Non-supervised.

Non-supervised training programs are based on an exercise protocol of increasing intensity that can be handed out to patients. These address to low-risk patients who have no ischemia, no arrhythmias, left ventricle function higher than 50% and a good functional capacity.

Supervised training programs take place in a CR unit and last two to six months. Here, the patient is guided as to how to do the exercises and receives educational and psychological support. This program represents a training period since patients are required to continue with the exercises, try to keep fit and control their risk factors after the program ends. Supervised training programs are divided in *intensive* and *ambulatory-based* (24).

- **Ambulatory-based supervised cardiac rehabilitation programs:** These last for three to six months in which the patients are required to go to the center to do the protocol of physiotherapic exercises three days a week. Patients also recieve week-

ly talks and the needed individual and group therapies (24).

- **Intensive supervised cardiac rehabilitation programs:** These are designed for patients with work responsibilities or who live far away from the rehabilitation center. It includes an in-patient period of three weeks in a center with full capacity for a CRP. The multidisciplinary treatment program consists in daily morning and afternoon sessions. The evenings as well as the weekend are off. In the end the patient receives a *report* with the details of the program, the level of physical activity he/she was able to accomplish as well as his or her overall management. After this initial learning period, the patient will continue with periodic periodic checkups with his/her doctor and the usual care provided by the health system (24).

Cardiac rehabilitation for special patients

Elderly patients should start with very short sessions with sufficient breaks in between. The progression towards higher exercise intensity must be slower and higher medical attention may be needed as well. The psychological aspects are of great importance in elderly patients, because depression and anxiety can have a major negative impact on patients older than 75 years. Following this carefully laid out programs have proven to improve quality of life in elderly patients as well (28).

Patients that are affected by invalidating osteomuscular pathologies can train exercising in the water, aqua gym and swimming for example.

Patients with chronic lung deficiency should start with respiratory physiotherapy and their oxygen saturation should be monitored during the exercises session.

Paraplegic patients should engage in exercises that only mainly require the upper part of the body, such as lifting weight.

Patients who underwent surgery are required to start with breathing exercises and slowly increase walking exercises in distance and intensity.

Sufficient evidence reveals that after *percutaneous revascularization* the protocol discussed above can be applied after two weeks from the intervention (29).

4.4. The intervention in practice

It has been more than 40 years since the WHO published the first recommendation about placing our patients in CRPs. Since then the indications for patients to be included in these programs have steadily increased. Nowadays CR is recommended for almost all patients with any type of coronary heart disease and most patients with heart failure as well as for patients after cardiac revascularization.

The aim of a CR is to improve the patient's quality of life, and, if possible, to improve patient's prognosis. There is sufficient evidence that CRP is safe, that is to say that these interventions don't increase mortality or morbidity. It is furthermore proven a statistically meaningful increase of patient's health related quality of life (HRQoL) for those who engage in CRP in randomized studies. As well as a diminishment in mortality, morbidity and hospital readmission both in short and long term studies (22).

CRPs require the coordination of many medical specialties and a real multidisciplinary teamwork. As a result, many patients who would need this kind of rehabilitation do not recieve it. Although there is the necessary equipment and infrastructure and excellent professionals in Spain, only a 3% of the population gets in a CRP (24).

5. JUSTIFICATION

Much research has been done supporting the inclusion of patients with heart failure (HF) or coronary heart disease (CHD) in a cardiac rehabilitation program (CRP). This research resulted in the publishing of many clinical trials as well as several meta analysis and systematic reviews. In conclusion, CRPs are strongly recommended in the key clinical guidelines of the ESC and the ACC/AHA.

The Cochrane Database of Systematic Reviews published in 2014 a review of CR trials that states that these programs have become a fundamental element to the standard care of patients with heart disease (22):

- CR in patients with HF or after myocardial infarction is safe, meaning it doesn't harm nor increase mortality.
- CR is effective to improve the health related quality of life (HRQoL) and to reduce the risk of hospital readmission.
- The benefit of the CRP is not dependent on the type of program or on the participant characteristics. Home-based and center-based programs seem to be equally effective.
- Psychological and educational-based interventions have little or no impact on mortality but they improve HRQoL of patients compared to exercise alone.

However, both the Cochrane review and the study OPTICARE from the SEC (24) recently published that most of the studies on CR so far have focused on a limited sample group. These mostly include young and low risk individuals: average of 60 old, with low risk for acute coronary syndrome, without systolic dysfunction and without comorbidities like chronic obstructive pulmonary disease (COPD), renal failure or peripheric vascular disease). This was the case, although the real picture of today is that the majority of candidates for a CRP are elderly and with advanced heart pathology (17,22). This points at a *limited external validity* for the studies run up to now.

The publications mentioned above have been the motivation for our study. We aim at expanding the results of the effectiveness of CR to a greater share of population. In particular, we are using a *randomized controlled trial* in order to test the positive effects of CR in

a more heterogeneous sample than it was used in these studies so far. This allows us to test previous results to individuals who typically have not been subjects of CRP trials.

In conclusion, the sample of our study allows us to test whether this treatment improves the health related quality of life (HRQoL) for *all patients* who could benefit from it.

Regarding the outcomes, we have chosen to analyze the *health related quality of life*. We know that the aim of CR is, by definition, to restore the patient to the optimal physical, psychological, economic and social status (WHO 1993), which in other words is defined as the quality of life. The quality of life measurement is, therefore, needed to demonstrate program-mediated chances in improving psychological and social well-being of the patients in an effort to determine effective and efficient rehabilitation strategies (31).

6. HYPOTHESIS

The hypothesis of this study is that the application of a cardiac rehabilitation program on *all patients* with coronary heart disease or heart failure improves their health related quality of life.

7. OBJECTIVES

The main objective of this study is to determine whether the application of a cardiac rehabilitation program for *all patients* with coronary heart disease or heart failure improves their health related quality of life.

The secondary objective is to organize and establish a CRP in *La Cerdanya*, our sample base. We have the aim that it will continue to work after this study has concluded. As previously discussed, in Spain CRP are only offered to a 3% of the patients who could actually benefit from it. This program would thus be a way of implementing this kind of interventions into practice, which follows the recommendations from *El Ministerio Español de Sanidad* (32).

8. METHODOLOGY

8.1. Study design

For this study we need the highest level of evidence, and this is obtained through a clinical trial. Therefore we have designed a *controlled and randomized clinical trial*.

We are not conducting a blind study here, since is impossible because the subjects will obviously know weather they are or not doing CR.

In this trial half of the recruited patients will get into a CRP and half will receive the standard care currently provided by our health system. The participant's quality of life will be assessed through a written questionnaire for two years.

8.2. Population of interest

The population of interest for this study includes all patients who suffer acute or chronic CHD or are currently under HF class I or II of the NYHA (as previously exposed, class III and IV are too severe and patients can't cope with any physical activity). All the participants are of those looked after in *Hospital de Cerdanya*.

We have defined the population of this study as follows:

8.2.1. Inclusion criteria

All adult patients attended in *Hospital de Cerdanya* who meet the next criteria:

- Have stable angina, or
- Have suffered from unstable angina or a myocardial infarction but have been medically or surgically treated and are currently clinically stable, or
- Suffer from heart failure (functional class I or II of the NYHA).
- All patients must have signed the informed consent.
- All patients who are assigned to participate in the CRP must go through a cardiac stress test and a medical assessment.

8.2.2. Exclusion criteria

- Patients with CHD in acute phase, with signs and symptoms of unstable angina or currently with an angina induced by effort.
- Patients with heart failure class III or IV of the NYHA.
- Patients who have contraindication for physical exercise.
- Patients who are unable to understand or remember instructions.

8.2.3. Withdrawal criteria

- Patients unwilling to attend the program.
- Patients who revoke the information consent.

8.3. Sample size

In this study we will compare two independent means: the mean of HRQoL of patients who attended a CRP compared to the mean of HRQoL of patients who did not. According to our power analyses the sample size should be of at least 496 patients to obtain statistically significant results. These patients will be randomly divided in two equal groups: 248 patients will receive the intervention and 248 will receive the standard care currently provided by the public health system for these conditions.

The expected sample size was estimated according to an alpha risk of 0.05 and a beta risk of 0.2. We are working with a unilateral contrast since it is proven that CR is safe: it does not harm nor decrease patient's quality of life. We assumed that 20% of the patients would leave the study. And the standard deviation of the test was assumed to be 20, based on previous studies (33).

We are looking for a difference of 5 units in the aggregate outcome of the quality of life test. This difference is clinically relevant in the following way: the test assesses eight life aspects, a difference of 5 points in the aggregate outcome translates into a moderate increase in one life aspect or a small increase in two of them (small change but clinically important) (34).

8.8. Methods of recruitment and randomization

From the clinical experience of the Internal Medicine Service in *Hospital de Cerdanya* we have concluded that we need around two years to get a sample of 496 patients with either CHD or HF.

First of all, there is a period of two months for recruiting the patients with these conditions by the Service of Internal Medicine. This two months period is for a good number of participants to start together the CRP. Both, inpatients of the hospital and patients who come to the outpatients visit between December 2016 and January 2017 who meet the inclusion criteria will be offered to enter the trial.

From then on, and for a period of two years, as patients get diagnosed they will be offered the option of entering the trial.

Enrolled participants are randomly assigned at a 1:1 ratio in two groups: *intervention group* which joins a CRP and *control group* which does not. The randomization process is conducted by the main investigator. And each patient will be assigned an identification number obtained by a number code generator to keep anonymity.

Patients who don't want to be randomly chosen are not allowed to participate in the study. Nevertheless, these patients are still allowed to follow a CRP, but they will not be part of our analysis since data could potentially suffer from *self-selection bias*.

Furthermore, every patient will receive an information sheet together with the informed consent and the recruitment questionnaire (*Annex II, III, IV*). All this will be read, understood and completed by the patient with the doctor's help and handed in to the main investigator.

8.6. Study variables

Independent variable: *to join a cardiac rehabilitation program*. This is a *dichotomous categorical variable*, since it has only two categories: to be included in a CRP or not.

Dependent variable: *patient's quality of life*. This is a *quantitative discrete variable*, since the quality of life questionnaire can only take values based on a count from a set of distinct whole values. We are calculating the aggregate outcome of the eight different life items the test assesses and it can take any integer from 0 to 100.

Covariates:

- *Gender* is a dichotomous qualitative variable (male/female).
- *Age* is measured in years; it is a discrete quantitative variable.
- *Basal diagnosis* is a nominal qualitative variable: coronary heart disease or heart failure.
- *Level of comorbidity* is a numeric discrete variable, measured through the Charslon Comorbidity Index (*Annex V*).

8.5. Study intervention: the Cardiac Rehabilitation Program

As explained, the benefits of CR are not dependent on the concrete characteristics of the program. We have taken the main guidelines from the SEC (24) and some other programs run all over Spain to organize the CRP we are going to start in *La Cerdanya* (35,36).

After the patients are informed about the trial and sign the consent to become a participant, they are randomly assigned in the two explained groups.

Patient's pre-evaluation: All patients must go through this pre- evaluation:

- Recruitment Questionnaire to get the patient's characteristics: gender, age, basal diagnosis, and Charlson comorbidity Index (*Annex II*).
- Filling up the SF-36 test (*Annex XI*).

Only for the patients assigned to participate in the CRP:

- Cardiac stress test: To ensure security, the patient must not exercise to a higher cardiac frequency of 75-80% of her/his maximum and we must know if there is risk of an arrhythmia or any inadequate response to PE.
- Psychological evaluation to better focus on the patient's needs during the psychological therapies.

The **CRP** starts for those patients assigned to participate in it. It has four phases.

PHASE 1 of the CRP: Education and counseling start immediately, even as an *inpatient*. At this point the exercise intensity is determined by the responsible doctor and it consists in arm movements, standing up from the bed and walking in the hall. The objective of this phase is to reduce the effects of long lying down.

PHASE 2 of the CRP: It takes place in the *convalescence period*, the PE level must be controlled and supervised by the responsible doctor. Counseling on CVRF start and possibly psychological support as well.

PHASE 3 of the CRP: Our CRP will last 24 weeks (six months): 12 weeks will be ambulatory based and 12 weeks will be patient's autonomous work (home-based).

During the first 12 weeks the patients will attend to:

- **Two days a week of a 60 minute session of exercises**. The patients will do a protocol of warming up, stretching, and light weight lifting for 15-20 minutes plus 40 minutes on the stationary bicycle or the treadmill with increasing intensity (up to 75-80% of the patient's maximum cardiac frequency registered in the cardiac stress test). This is completed at home with regular daily exercise of 30-40 minutes every day. This home-based part is very important for future adherence. To this end, we will facilitate an illustrated booklet with the exercises the patients have to do every day at home (*Annex VI*).
- **A weekly 40 minute educative talk** on basic characteristics of the diseases they suffer, the importance of treatment adherence and the relevance of CVRF and how to treat them. The subjects of the 24 talks that will take place during the whole program are already definite (*Annex VII*).

- **A weekly 60 minute group therapy session** including a training in relaxation techniques. Individual therapy will be given to those patients who require it based on the assessment by the psychologist.

During the program, the patient is monitored by the nurse or doctor (available during all the exercise sessions to assure security) and the therapist (who is in charge of both the psychological support and the educative talks).

For the next 12 weeks the patient is supposed to be autonomous regarding PE and continue with the regular daily exercise of 30-40 minutes per day. Educative talks and group therapy continue to take place once a week.

Following the patient during the program: during the program the patient is controlled by the doctor and the psychologist ensuring security and proper enactment of the program. Exercises progression is specially controlled and registered in a sheet of paper using the *Borg scale* of perceived exertion (*Annex IX - X*).

Patient's post-program evaluation: Six month after having started in the trial both intervention and control group fill up the *SF-36* test again. This is in order to assess the short-term effects of the CRP.

PHASE 4 of the CRP: corresponds to the permanent and not supervised PE the patients must realize after the supervised CRP has finished. It consists in 30-40 minutes of moderate PE per day as was trained. In order to make this last phase successful, during the program it is important to provide the participants with skillful means and increase long-term motivation.

Patient's follow-up: We want to assess the patient's HRQoL for a period of two years since the beginning of the study to see if changes in HRQoL last for this period of time. All patients fill up the SF-36 after one and two years of the trial start.

For the patient to have successfully completed the CRP it is necessary to have signed in 70% of the educational talks, 70% of the group therapy and relaxation session and the 80% of the PE sessions (the attendance control sheet is in *Annex VIII*).

8.7. Measure instruments

The QoL measures are increasingly becoming accepted as useful assessment tools and are definitely a suitable outcome measures in cardiac rehabilitation.

The Health related quality of life (HRQoL) includes: physical impairment and symptoms, functional status both physical and emotional, as well as satisfaction and social functioning in work, leisure, social life, family and sexual activity (37).

There are a number of tools to measure HRQoL: *generic instruments* and *disease-specific instruments* represent the two basic available approaches (31):

- *Generic instruments* aim to be comprehensive covering a wide range of life domains and to be applicable to many illness groups:
    - *Health profiles* are single instruments that measure several separate aspects of the quality of life. Although sometimes the scores can also be combined into a single index.
    - *Utility measures* involve the patient estimating his/her QoL along a continuum from death to full health. However, these have been subject to much criticism over the last few decades.
- *Specific instruments* focus on symptoms and problems that are specific to a particular medical condition or to assess a particular body function.

In this study we are using a *generic instrument* since our patients suffer from a variety of different medical conditions, and thus, *health profiles* are the best choice for our subject matter.

The most commonly used health profiles in heart disease are: the *Nottingham health profile* which is used approximately in 40% of studies, the *Short form 36 (SF-36)* which is used in 24% of studies, and the *Sickness impact profile* which is also used in the 24%. Dempster and Donnelly stated that of the three generic measures, the *SF-36* appears to offer the most reliable, valid and sensitive assessment of the quality of life (38).

Besides that, and very suitable for our subject matter, a study compared the SF-36 and the NHP in the context of CR (31). The results suggested that the SF-36 is a better measure of quality of life in this concrete situation as well. The scales of the SF-36 appear to be more

sensitive, have higher internal consistency coefficients, and give clearer evidence of discriminant validity than the NHP.

All this information confirmed that the *SF-36* should be the preferred instrument when measuring the quality of life in CR.

8.7.1. The Short Form 36 (*Annex XI*)

The SF-36 is a generic multidimensional instrument consisting of eight items:

- *Physical functioning*: the extent to which health limits physical activities such as self care, walking or climbing stairs;
- *Role functioning physical*: the extent to which physical health interferes with work or other daily activities;
- *Bodily pain*: the intensity of pain and the effect of pain on normal work;
- *General health perception*: personal evaluations of current health, health outlook and resistance to illness;
- *Vitality*: feeling full of energy rather tan tired and worn out;
- *Social functioning*: the extent to which physical health or emotional problems interfere with normal social activities;
- *Role functioning emotional*: the extent to which emotional problems interfere with work or daily activities;
- *Mental health*: general mental health including depression, anxiety, behavioral-emotional control and general positive affect.

Each of these scales have a possible range of scores of 0-100 and a high score indicates a better health state. In order to calculate the QoL score of every item, it is necessary to first homogenize the direction of the answers so all items follow the rule "higher punctuation, better health state", then to sum the different items of the scale and finally to do a linear transformation to obtain numbers between 0 and 100 for every scale (39).

Normally this test is evaluated by separately analyzing the eight different aspects, but, as explained in more detail in the next section, in this study the dependent variable is the *aggregate outcome* of all the different aspects, this is calculated through the mean of these eight items.

9. STATISTICAL ANALYSIS

The main analysis will be performed using a regular *Student's t-test*, which is a parametric test that assumes the variables to be normally distributed. We will contrast these results to those obtained by the *Mann-Whitney test*, which drops the normality assumption and therefore is a more conservative test.

We will also perform an *Ordinary Least Square (OLS) regression* that will allow us to find the effect of the CRP on the patient's HRQoL, while controlling for all the covariates: sex, age, basal diagnosis and level of comorbidity.

As previously pointed out, the SF-36 test is a generic health profile consisting of eight items scored from 0 to 100: physical functioning, role functioning, bodily pain, general health perception, vitality, social functioning, role functioning emotional and mental health. These items are normally analyzed separately, although sometimes they can be combined into a single score.

Our dependent variable is the *aggregated score of HRQoL*, which is a score ranging from 0 to 100 that is compounded by the eight different questionnaire items. The main result will be a regression where HRQoL differences between the treatment and the control group are explained and controlled by the four covariates. To this end, the data will be analyzed using SPSS.

To make a more detailed analysis, we will proceed to use the same explanatory variables to explain every one of the eight different components of the HRQoL test. This means that there will be a regression for every one of the eight items as well controlled by the covariates.

This in turn will allow us to conclude at the same time: whether the treatment has positive effects for patient's QoL overall and which components of this index are especially beneficial.

10. ETHICAL ASPECTS

This study has been carried out according to human rights and the ethical principles for medical research described by the World Medical Association Declaration of Helsinki, last revised in October 2013.

All patients will be properly informed of the trial's objectives and interventions before joining the trial (*Annex II*). It is imperative that they read and understand the information before they are asked to sign the informed consent (*Annex III*). And their autonomy will be respected, not only before entering the trial but at all times.

Participant's information will be confidential, guaranteeing anonymity, in accordance to the *Ley Organica 15/1999 de 13 de diciembre de Protección de Datos de Carácter Personal*.

The study has been presented to the "Comitè d'Ètica de l'Hospital de Cerdanya" to be evaluated and is now pending approval.

We declare no conflict of interest of any kind.

11. LIMITATIONS

The main limitation in our opinion is that this is *an open label trial*: patients know whether they are attending a CRP or not. In the same direction the recruitment process might be another problem since it is possible that many patients refuse to be randomly assigned because they prefer either to take a CRP or not. If this means a real problem during the study, we could consider not offering the option of joining the CRP if it is not as part of the study and according to randomization.

A third evident limitation is that we cannot warrantee our results can be extrapolated to other regions or countries. However randomization of patients and using validate questionnaires increase reliability to extrapolate outcomes to other populations.

Another limitation might be the reduced following up of patients, we are controlling changes in HRQoL only for two years. This might be a valid objective for future studies: to find the way of having a longer effect on the better quality of life of the patients.

Since we are assessing QoL we have to be aware that it can easily be affected by many uncontrollable factors, for example, season changes affect tiredness and capability of exercising and personal and family problems affect emotional status. We aim on following our patients over a period of two years to minimize these confusions factors, but we have to be aware these could still affect our data.

Another important limitation of this study is the fact that many of these conditions progress over time and can considerably deteriorate the patient's state, this could be a *confusion variable*. In the same direction lost to follow-up may be a limitation since most of our patients are old and can become unable to exercise or die.

Finally, our estimations conclude that we need around two years to obtain 248 patients with the mentioned characteristics in the population covered by *Hospital de Cerdanya*. In the case this was not possible or with the intention of reducing the recruitment period we could consider a multicenter study. The problems in this case would be the higher variability of the approaches, the more difficult organization and the higher costs.

12. WORK PLAN AND CHRONOGRAM

This study is expected to last 4 years and 2 months, and is organized in 4 stages:

STAGE 1: Preparation and coordination (3 months). COMPLETED.

The first stage has been to elaborate the protocol, define the variables and the study work plan, this took place from September 2016 to November 2016. The entire team met to specify everyone's task and create the chronogram in collaboration (available in the next page). The researches will meet regularly every three months during the whole period in order to control and assess the progression of the trial. The study has been presented to the ethical committee and is pending approval.

STAGE 2: Field research (4 years) *December 2016 to February 2021*.

Sample collection: patients meeting the inclusion and exclusion criteria who come to *Hospital de Cerdanya* and are willing to take part in the study will be invited to sign the informed consent and join the trial (*Annex III-IV*).

Intervention: *Patients in the control group* will receive the standard care currently provided by the health system. *Patients in the intervention group* will take a cardiac stress test, a psychological evaluation and start the six months CRP.

Quality of life questionnaire **and follow up:** all patients must fill up the *SF-36 questionnaire* in four occasions: in the *Week 1*, in the *Week 24* (right after the program has finished for the patients in the intervention group), in the *Week 48* (one year) and in the *Week 96* of the program (two years).

STAGE 3: Data collection and analysis (3 months) *February 2021 to April 2021.*

The data collected from each patient during the trial will be introduced in our database and analyzed by our statistical specialist.

STAGE 4: Interpretation, publication and dissemination (one year and a half)

Our main investigator will interpret the results and write the conclusions in the corresponding article. After this, the paper must be published and disseminated. This is planned to happen between *May 2021 to August 2022.*

Tasks	2016			2017			2018		2019			2020		2021					2022		
	Sept	Nov	Dec	Jan	Feb	Dec	Jan	Dec	Jan	Feb	Dec	Jan	Dec	Jan	Feb	April	May	Dec	Jan	Mai	Aug
PHASE 1: PREPARATION AND COORDINATION																					
Protocol elaboration and evaluation																					
Coordination of research team																					
PASE 2: RECRUITMENT AND FIELD RESEARCH																					
Two months recruitment																					
Continuous recruitment																					
Cardiac rehabilitation program																					
PHASE 3: DATA COLLECTION AND ANALYSIS. RESULTS AND CONCLUSIONS																					
Data collection and analysis																					
Quality assurance and control																					
Discussion of results and conclusions																					
PHASE 4: PUBLICATION AND DISSEMINATION																					
Publication of the article																					
Conferences and congresses																					

15. BUDGET

To calculate the needed budget for this trial we have divided the costs in human needs, material and publication costs.

We need one nurse or doctor to be present while the exercise sessions take place to control and care for the patients (2 hours a week; 384 hours in total). The psychologist will take care of the psychological support and will also hold the educative talks (5 h per week; 960 hours in total). The statiscian expert is in charge of analyzing the data, this will happen at the end of the study for about 100 hours. We also need skilled staff to carry out the data monitoring and quality control (2 hours a month; around 80 hours). Our graphic designer is working on the exercises booklet for better understanding and adherence to the home-based program (15 hours).

We count on some material for the exercises: we need weights, matrasses, four treadmills and four stationary bicycles, and some blood pressure manual monitors.

We ask for 71.950 € in total but we expect *El Ministerio de Sanidad y Consumo* to refund and take responsibility of 60.000 € of it. When our requests and applications go through, we will be certified to carry this project and won't have to pay for the worker's salaries but only the inherent costs to the study (quality control, statiscian and publication costs). **Thus**, ***the real cost of this project is 11.950 €***.

STAFF		
Nurse or Doctor	384 h x 50 €/hour	19.200 €
Psychologist	768 h x 50 €/hour	38.400 €
Statiscian	100 h x 50 €/hour	5.000 €
Quality control	80 h x 50 €/hour	4.000 €
Graphic designer	15 h x 50 €/hour	750 €
MATERIAL		
Printing and papers		100 €
Material: weights, exercise machines, blood pressure monitors		1.000 €
PUBLICATION AND DISSEMINATION		
Publication costs		2.000 €
Congress costs (registration, travelling, accommodation)		1.500 €
TOTAL		**71.950€**

14. FEASIBILITY AND IMAPCT OF THIS PROJECT ON THE HEALTH SYSTEM

The realization of a CRP follows the recommendation from the *SEC* and *El Ministerio de Sanidad,* therefore, it will not be a problem to get the permission to start this project. We are very confident that this project will go ahead since its commonly known, and recently in 2016 the ESC stated, that prevention of CVD is cost effective in actions directed at high-risk individuals.

The proposed study will take place in Puigcerdà, *la Cerdanya*, where all the needed means for the study development will be available.

We have been offered a big room that belongs to the city hall where all the activities can be held, in *Hospital de Cerdanya* we count on two doctors who have already agreed to be in charge of looking after the patients while they are in the exercise sessions. We will contract a psychologist who will take care of all the psychological support and will be in charge of the educative talks.

A data base has been created in which the characteristics of the patient that can be registered, and, as said, we will hire a statiscian who will be responsible of the statistical analysis and data processing. Our graphic designer is already working on the booklets to give to the patients when they start the home-based exercises program, since they must be clear, with enough pictures, and easy to understand for better adherence.

And the main investigator is in charge of interpreting the results and writing the final article, as well as its publication and dissemination.

Patients with heart disease need these rehabilitation programs to start in their hometowns. And such thing is possible, they are cheap to the health system and it does only good to the patients.

15. BIBLIOGRAPHY

1. Montalescot G, Sechtem U, Achenbach S, Andreotti F, Arden C, Budaj A, et al. 2013 ESC guidelines on the management of stable coronary artery disease. Eur Heart J. 2013;34(38):2949–3003.

2. Mendis S, Puska P, Norrving B. Global atlas on cardiovascular disease prevention and control. World Heal Organ. 2011;2–14.

3. Rozman C, Farreras. Farreras-Rozman: Medicina Interna [Internet]. 2014. 211-215 p. Available from: http://tienda.elsevier.es/farreras-rozman-medicina-interna-acceso-online-pb-9788480868969.html

4. Kumar A, Cannon CP. Acute coronary syndromes: diagnosis and management, part I. Mayo Clin Proc [Internet]. 2009;84(10):917–38. Available from: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2755812&tool=pmcentrez&rendertype=abstract

5. World Heart Federation. Cardiovascular Disease Risk Factors. Cardiol J [Internet]. 2012;(April 2012):6–9. Available from: http://www.world-heart-federation.org/fileadmin/user_upload/documents/Fact_sheets/2012/PressBackgrounderApril2012RiskFactors.pdf

6. Piepoli MF, Hoes AW, Agewall S, Albus C, Brotons C, Catapano AL, et al. 2016 European Guidelines on cardiovascular disease prevention in clinical practice. Eur Heart J. 2016;37(29):2315–81.

7. Ramos R, Solanas P, Cordón F, Rohlfs I, Elosua R, Sala J, et al. Comparación de la función de Framingham original y la calibrada del REGICOR en la predicción del riesgo coronario poblacional. Med Clin (Barc). 2003;121(14):521–6.

8. Calculadora de risc cardiovascular REGICOR [Internet]. Available from: https://www.imim.cat/ofertadeserveis/software-public/regicor/?1

9. Mancia G, Fagard R, Narkiewicz K, Redon J, Zanchetti A, Böhm M, et al. 2013 ESH/ESC guidelines for the management of arterial hypertension: The Task Force for the management of arterial hypertension of the European Society of Hypertension (ESH) and of the European Society of Cardiology (ESC). Eur Heart J. 2013;34(28):2159–219.

10. Roffi M, Patrono C, Collet J-P, Mueller C, Valgimigli M, Andreotti F, et al. 2015 ESC Guidelines

for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation. Eur Heart J. 2016;37(3):1101–6.

11. Grace 2.0 : Calculator [Internet]. Available from: http://www.gracescore.org/website/WebVersion.aspx

12. Nichols M, Townsend N, Luengo-Fernandez R, Leal J, Gray A, Scarborough P, et al. European cardiovascular disease statistics 2012. European Heart Journal. 2012. 129 p.

13. Dégano IR, Elosua R, Marrugat J. Epidemiology of Acute Coronary Syndromes in Spain: Estimation of the Number of Cases and Trends From 2005 to 2049. Rev Española Cardiol (English Ed. 2013;66(6):472–81.

14. Grau M, Subirana I, Vila J, Elosua R, Ramos R, Sala J, Dégano IR, Tresserras R, Bielsa O MJ. Validation of a population coronary disease predictive system: the CASSANDRA model. J Epidemiol Community Heal. 2014;(68).

15. Tomàs L, Lorenzo CV, Pérez I, Puig T, Balaguer I. Factores de riesgo y morbimortalidad coronaria en una cohorte laboral mediterránea seguida durante 28 años. Estudio de Manresa. Rev Esp Cardiol [Internet]. 2001;54(10):1146–54. Available from: http://www.revespcardiol.org/es/factores-riesgo-morbimortalidad-coronaria-una/articulo/13019364/

16. Alonso J, Muñiz J, José Gomez-Doblas J, Rodríguez-Roca G, María Lobos J, Permanyer-Miralda G, et al. Prevalencia de angina estable en España. Resultados del estudio OFRECE. 2014;67(4):259–69.

17. O'Callaghan. The REGICOR Registry and the Epidemiology of Myocardial Infarction in Spain : Forging a Path. 2007;60(4):25–8.

18. Ferreira-González I. The epidemiology of coronary heart disease. Rev Esp Cardiol (Engl Ed) [Internet]. 2014;67(2):139–44. Available from: http://www.sciencedirect.com/science/article/pii/S1885585713003381

19. Ponikowski P, Voors AA, Anker SD, Bueno H, Cleland JGF, Coats AJS, et al. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. Eur Heart J. 2016;37(27):2129–2200m.

20. Mosterd A, Hoes AW. Clinical epidemiology of heart failure. Heart. 2007;93(9):1137–46.

21. Maggioni AP, Dahlström U, Filippatos G, Chioncel O, Leiro MC, Drozdz J, et al.

EURObservational Research Programme: Regional differences and 1-year follow-up results of the Heart Failure Pilot Survey (ESC-HF Pilot). Eur J Heart Fail. 2013;15(7):808–17.

22. Anderson L, Taylor R. Cardiac rehabilitation for people with heart disease: an overview of Cochrane systematic reviews. Cochrane Libr. 2014;(12):51.

23. Steg PG, James SK, Atar D, Badano LP, Lundqvist CB, Borger MA, et al. ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation. Eur Heart J. 2012;33(20):2569–619.

24. José M.ª Maroto Montero. Rehabilitacion Cardiaca. Secar [Internet]. 2009;113. Available from: http://secardiologia.es/images/publicaciones/libros/rehabilitacion-cardiaca.pdf

25. Taylor RS, Brown A, Ebrahim S, Jolliffe J, Noorani H, Rees K, Skidmore B, Stone JA, Thompson DR ON. Exercise-based rehabilitation for patients with coronary heart disease: systematic review and meta-analysis of randomized controlled trials. American Journal of Medicine. 2004;682–92.

26. Dusseldorp E, Van Elderen T, Maes S, Meulman J K V. A meta-analysis of psychoeducational programs for coronary heart disease patients. Heal Psychol. 1999;(18):506–19.

27. Mats Gulliksson, MD, PhD; Gunilla Burell, PhD; Bengt Vessby, MD, PhD; Lennart Lundin, MD P, Henrik Toss, MD, PhD; Kurt Svärdsudd, MD P. Randomized Controlled Trial of Cognitive Behavioral Therapy vs Standard Treatment to Prevent Recurrent Cardiovascular Events in Patients With Coronary Heart Disease. 2011;

28. Pasquali SK, Alexander KP, Peterson ED. Cardiac rehabilitation in the elderly. Am Heart J. 2001;142(5):748–55.

29. Belardinelli RB, Paolini P, Cianci GCG, Piva RPR, Solenghi MSM. The efficay of exercise training after coronary angioplasty: the ETICA trial. Eur Heart J. 2001;22(7):200.

30. Lo mejor del ESC 16. Estudio OPTICARE [Internet]. Available from: http://secardiologia.es/multimedia/blog/rec/7864-lo-mejor-del-esc-16-estudio-opticare

31. Dempster M, Bradley J, Wallace E, Mccoy P. Measuring quality of life in cardiac rehabilitation : comparing the Short Form 36 and the Nottingham Health Profile. Coron Hear Care. 1997;1:211–7.

32. Castro A. Estrategia en Cardiopatía Isquémica del Sistema Nacional de Salud. Actualización aprobada por el Consejo Interterritorial del Sistema Nacional de Salud el 22 de octubre de 2009. Minist Sanidad, Política Soc E Igual [Internet]. 2011; Available from: http://www.mspsi.gob.es/organizacion/sns/planCalidadSNS/docs/cardiopatia_isquemica/Estrategia

_Cardiopatia_Isquemica.pdf

33. Juenger J, Schellberg D, Kraemer S, Haunstetter A, Zugck C, Herzog W, et al. Health related quality of life in patients with congestive heart failure: comparison with other chronic diseases and relation to functional variables. Heart. 2002;87:235–41.

34. Wyrwich KW, Tierney WM, Babu AN, Kroenke K, Wolinsky FD. A comparison of clinically important differences in health-related quality of life for patients with chronic lung disease, asthma, or heart disease. Heal Serv Res [Internet]. 2005;40(2):577–91. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15762908

35. DR. GERARD BURDIAT RAMPA. Programa práctico de Rehabilitación Cardiovascular. Rev Urug Cardiol [Internet]. 2006;21:240–51. Available from: http://www.suc.org.uy/revista/v21n3/pdf/rcv21n3_8.pdf

36. Fernández Luque F, Mora Robles J, Cantador Hornero M, Soto Sánchez, Joaquina M. Guía de ejercicios para pacientes con enfermedad cardiovascular. Serv Andaluz Salud Hosp Reg Málaga [Internet]. 2014;(Unidad de Rehabilitación Cardiaca UGC de Medicina Física y Rehabilitación Unidad del Corazón y Patología Vascular Hospital Regional Universitario de Málaga). Available from: http://www.hospitalregionaldemalaga.es/LinkClick.aspx?fileticket=fQxdjij67AU%3D&tabid=887

37. Mayou R, Bryant B. Quality of life in cardiovascular disease. Br Heart J. 1993;69:460–6.

38. Dempster M, Donnelly M. Measuring the health related quality of life of people with ischaemic heart disease. Heart. 2000;83:641–4.

39. Vilagut G, Ferrer M, Rajmil L, Rebollo P, Permanyer-Miralda G, Quintana JM, et al. El Cuestionario de Salud SF-36 español: una década de experiencia y nuevos desarrollos. Gac Sanit. 2005;19(2):135–50.

16. ANNEXES

ANNEX I - CLASSES OF RECOMMENDATION AND LEVELS OF EVIDENCE

CLASSES OF RECOMMENDATION

Class I: Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective. It is recommended/ it is indicated.

Class II: Conflicting evidence and/or a divergence or opinions about the usefulness/efficacy of the gven treatment or procedure.

Class IIa: Weight of evidence/opinión is in favor of usefulness/efficacy. Should be considered.

Class IIb: Usefulness/efficacy is less well established by evidence/opinión. May be considered.

Class III: evidence or general agreement that the given treatment or procedure is not usedul/effective and in some cases may be harmful.

LEVELS OF EVIDENCE

Level A: Data derived from multiple randomized clinical trial sor meta-analyses.

Level B: Data derived from a single randomized clinical trial or large non-randomized studies.

Level C: Consensus of opinión of the experts and/or small studies, retrospective studies, registries.

ANNEX II - CHARLSON COMORBIDITY INDEX

Score	Condition
1	Myocardial infarction (history, not ECG changes only) Congestive heart failure Peripheral vascular disease (includes aortic aneurism from 6 cm) Cerebrovascular disease (CVA with mild or no residua or TIA) Dementia Chronic pulmonary disease Connective tissue disease Peptic ulcer disease Mild liver disease (whithout portal hypertension, includes chronic hepatitis)
2	Hemiplegia Moderate or severe renal disease Diabetes with end-organ damage (retinopathy, neuropathy, nephropathy or brittle diabetes) Tumor without metastases (exclude if more tan 5 from diagnosis) Leukemia (acute or chronic) Lymphoma
3	Moderate or severe liver disease
6	Metastasic solid tumor AIDS (not just HIV positive)

Charlsons comorbidity Index is the sum of all the different scores.

Generally: *0-1 points* is considered absence of comorbidity.

2 points is low comorbidity.

3 or more points is high comorbidiry.

ANNEX III- PARTICIPANT'S INFORMATION SHEET

UNIDAD DE REHABILITACIÓN CARDÍACA

HOJA DE INFORMACIÓN AL PARTICIPANTE

Proyecto: CARDIAC REHABILITATION IMPROVES THE QUALITY OF LIFE OF PATIENTS WITH CORONARY HEART DISEASE OR HEART FAILURE

Usted está invitado a participar en un estudio clínico sobre rehabilitación cardíaca.

Por favor, tome su tiempo para leer ésta información. Es importante que la comprenda y que haga cualquier pregunta que tenga al respecto. Cuando haya leído este documento, y si está de acuerdo, deberá proseguir con el consentimiento informado y el cuestionario necesario para entrar en el estudio.

Muchas gracias.

El propósito de este estudio es ver la efectividad en mejorar la cualidad de vida después de un programa de rehabilitación cardíaca para los pacientes con indicación para ella.

Las intervenciones de este estudio son dos: la mitad de los pacientes serán asignados a un programa de rehabilitación cardíaca que durará 6 meses y la otra mitad seguirá el protocolo de atención y cuidados habitual que se sigue en nuestro sistema de sanidad pública.

Los participantes serán asignados aleatoriamente en un grupo u el otro, como es habitual hacerlo en éste tipo de estudio, dado que queremos comparar la efectividad de dicha intervención y, por lo tanto, no es indicado controlar a qué grupo entra cada participante.

La duración de este estudio, para usted, es de dos años. Esperamos tener los resultados del estudio completo, ya analizados y listos para su publicación, en 2021.

En este estudio participaran 496 pacientes. Para usted, igual que para todos ellos, la **participación es totalmente voluntaria y no remunerada.** Si usted acepta participar en él será incorporado en uno de los grupos de estudio de forma aleatoria. Usted podrá reti-

rarse del estudio cuando quiera y sin dar explicaciones incluso si había aceptado la participación con anterioridad. El revocamiento de la participación en este estudio, en cualquier momento, no repercutirá en los cuidados médicos que le pertenecen por nuestro sistema de salud pública.

Sus responsabilidades al aceptar tomar parte en este estudio son: seguir las instrucciones que se le darán a continuación, acudir al programa de rehabilitación cardíaca si así se lo indican, rellenar y contestar los cuatro cuestionarios sobre su propia calidad de vida que se le proporcionarán en los momentos indicados durante estos dos años e informar de cualquier problema o duda que le surja durante el estudio.

La información recogida será estrictamente confidencial. Todos los datos de carácter personal quedan introducidos en una base de datos computarizada para su análisis y protegidos de acuerdo con la legislación vigente sobre protección de datos de carácter personal (Ley Orgánica 15/1999 de 13 de diciembre). Nadie, excepto su médico personal y el personal investigador podrá acceder a ellos. Únicamente las autoridades sanitarias podrían acceder a ésta información, si así lo solicitan.

Como resultado de este estudio esperamos tener un mejor conocimiento de cómo tratar y prevenir complicaciones en pacientes con enfermedad coronaria o insuficiencia cardíaca. Estos resultados se utilizarán para su presentación en congresos médicos o la publicación en revistas científicas. Podrán también ser útiles para el diseño de futuras metodologías y posibilidades de tratamiento.

Puede contactar, en cualquier momento, con su médico responsable en éste estudio y, por favor, no dude en hacernos cualquier pregunta al respecto.

Muchas gracias.

ANNEX IV– INFORMED CONSENT

UNIDAD DE REHABILITACIÓN CARDÍACA

HOJA DE CONSENTIMIENTO INFORMADO

Proyecto: CARDIAC REHABILITATION IMPROVES THE QUALITY OF LIFE OF PATIENTS WITH CORONARY HEART DISEASE OR HEART FAILURE

Yo, ……

Confirmo que:

He leído y entendido la hoja de información que se me ha entregado. He recibido suficiente información sobre el estudio.

He podido hacer preguntas sobre el estudio, y han sido respondidas de manera satisfactoria.

He hablado con ……....

Comprendo que la participación es voluntaria y que puedo retirarme del estudio cuando quiera sin dar explicaciones y sin que ello repercuta en los cuidados médicos que me pertenecen. En consecuencia:

Doy mi conformidad para entrar y ser participante en este estudio.

Permito al personal del estudio que consulte mi historia clínica, si es necesario, para confirmar datos. Y permito que todos los datos recopilados sean utilizados en investigaciones futuras.

Lugar y fecha:

Firma del participante:

Documento de Identidad del participante (**DNI**):

Firma del investigador:

ANNEX V- RECRUITMENT QUESTIONNAIRE

UNIDAD DE REHABILITACIÓN CARDÍACA

CUESTIONARIO PARA ENTRAR EN EL ESTUDIO:

CARDIAC REHABILITATION IMPROVES THE QUALITY OF LIFE OF PATIENTS WITH CORONARY HEART DISEASE OR HEART FAILURE

En éste cuestionario se le pregunta sobre sus datos personales y sobre su estado de salud. Rellene la información preguntada y marque la casilla correcta con una cruz cuando sea necesario.

Puede escoger realizer este questionario en *català* o en *castellano*.

Fecha de realización del questionario: ___ /___ /_____.

Sexo: Mujer ( ) Hombre ( )

Nombre:

Primer apellido:

Segundo apellido:

Fecha de nacimiento: ___ /___ /_____.

Su medico le ayudará a rellenar éstos apartados:

Diagnóstico basal:	Enfermedad coronaria ( )	Angina estable ( )
		Angina inestable tratada ( )
		Angina de esfuerzo tratada ( )
		Infarto de miocardio ( )
	Insuficiencia cardíaca ( )	Grado funciona I ( )
		Grado functional II ( )

Índice de comorbilidad de Charlson: ____

ANNEX VI – EXERCICES PROGRAM

UNIDAD DE REHABILITACIÓN CARDÍACA

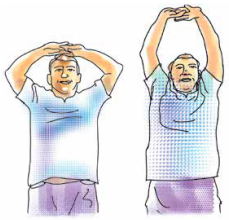
PROGRAMA DE EJERCICIOS EN CASA

1. **Ejercicios de calentamiento**

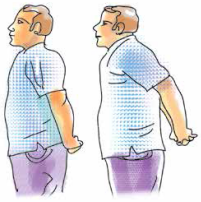
Lateralización de cuello: cuellos alineados y hombros relajados, acercar la oreja hacia el hombro y volver a la línea media. Serie de 5 veces.

Diagonal de cuello: relajar los hombros, llevar la mirada hacia arriba y a la izquierda y después hacia abajo y a la derecha. Repetir en sentido contrario. Serie de 5 veces.

Flexión de hombros: Cruzar las manos sobre la cabeza. Extender los codos llevando las palmas hacia el techo. Serie de 5 veces.

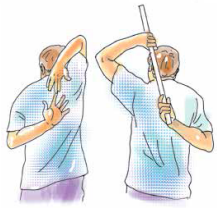


Extensión de hombros: entrelazar las manos con los brazos extendidos detrás del cuerpo. Realizar una separación de las manos de la espalda y volver a la posición inicial. Serie de 5 veces.



Estiramiento de pectorales: manos apoyadas en la nuca y con los dedos entrelazados abrir y cerrar los codos. Serie de cinco veces.

Rotadores de hombro: un brazo por arriba y otro por abajo, unir las manos con un palo o calcetín si no se llega y desplazar hacia arriba y hacia abajo las dos manos a la vez. Serie de 5 veces.



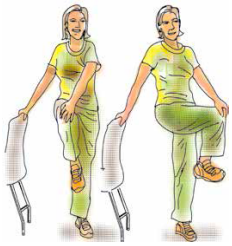
Estiramiento de miembros superiores: separar brazos abajo y subir brazos arriba para cruzarlos. Serie de 5 veces.

Lateralización del tronco: inclinar el tronco con el brazo extendido hacia un lado cogiendo aire. Repetir hacia el otro lado. Serie de 5 veces.

Giros de cintura: con las manos en la cintura.

Estiramiento miembros inferiores: apoyarse sobre superficie estable, levantar una pierna y separarla haca el lado y luego hacia delante. Cambiar de pierna. Serie de 5.

Estiramiento de separadores y rotadores: apoyar sobre una superficie estable, flexionar la pierna del y llevarla hacia dentro. Cambiar de pierna. Serie de 5.



Estiramiento de cuádriceps: apoyar sobre una superficie estable, coger el pie y llevar el talón hacia el muslo. Cambio de pierna. Serie de 5 veces.

Sentadilla: de pie con las piernas alineadas realizar una flexión y extensión de piernas como si se fuera a sentar en una silla y luego levantarse. Serie de 5 veces.

Rotaciones de cadera: tocar con la mano el talón del mismo pie por delante y luego por detrás. Cambio de pierna. Serie de 5.

Estiramiento de la cara anterior de la pierna: Ponerse de puntillas. Serie de 5 veces.

Estiramiento de gemelos: avanzar una pierna, dejando la de atrás extendida, ir hacia delante sintiendo una ligera tensión en la pantorrilla. Serie de 5.

Estiramiento de isquiotibiales: apoyar la pierna estirada en una superficie estable y flexionar el pie hasta que sienta presión en la pantorrilla. Serie de 5.

2. **Ejercicios de brazos con mancuernas o libre de peso**

Deltoides: sujetando un ligero peso subir ambos brazos a 90 grados. Serie de 10.

Trapecios: sujetando un ligero peso con los brazos en candelabro llevarlos hacia delante. Serie de 10.

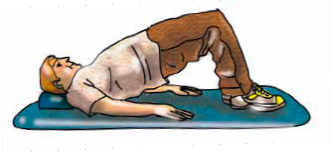
Pectorales: sujetando un ligero peso y con los brazos flexionados unir las manos delante del pecho. Serie de 10.

Bíceps: sujetando un ligero peso y con los brazos ligeramente separados del cuerpo llevarlos al cuello. Serie de 10.

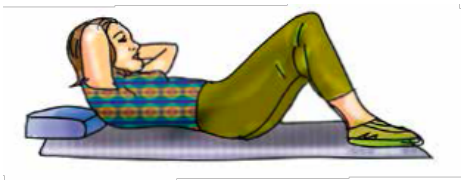
Tríceps: sujetando un ligero peso y con los brazos pegados al cuerpo levantarlos hacia arriba. Serie de 10

3. Ejercicios en colchoneta

Puente: subir las caderas separando los glúteos del suelo y bajar. Serie de 10.



Abdominales I: despegar los hombros del suelo sin tirar del cuello, al subir echar el aire y cogerlo al bajar. Serie de 10.



Abdominales II: inclinar el cuerpo para ir a tocar con la mano el tobillo del mismo lado y volver al centro. Repetir hacia el otro lado. Serie de 10.

Abdominales III: flexionar y extender alternativamente ambas piernas de forma coordinada. Serie de 10.

Estiramiento de isquitibiales: apoyar una pierna sobre la otra rodilla y subirla a extensión, después bajar lentamente. Serie de 10.

Flexión y extensión de tobillos: flexionar y extender tobillos al limite de movimiento. Serie de 10.

4. Ejercicios aeróbicos

Realizar ejercicios aerobicos de intensidad moderada un mínimo de 30 minutos cada día. O bien 45-60 minutos cinco días a la semana.

La mas sincera gratitud a los autores de "*Guía de ejercicios para pacientes con enfermedad cardiovascular*" de la *Unidad de Rehabilitación Cardíaca* del *Hospital Regional Universitario de Málaga* por prestarnos estas bonitas ilustraciones.

ANNEX VII – EDUCATIVE TALK PROGRAM

UNIDAD DE REHABILITACIÓN CARDÍACA

PROGRAMA DE CHARLAS EDUCATIVAS

Durante el programa ambulatorio

1. Introducción al programa de rehabilitación cardíaca
2. Cómo es y cómo funciona el corazón
3. Introducción a la enfermedad cardiovascular estable
4. Empeoramiento de la enfermedad coronaria y cómo detectarla
5. Introducción a la insuficiencia cardíaca
6. Convivir con tu corazón
7. El estilo de vida que necesita tu corazón y factores de riesgo cardiovascular
8. Ejercicio físico y corazón
9. Estrés y corazón
10. Técnicas de afrontamiento del estrés
11. Dudas y debate
12. Cómo seguir con el programa de ejercicios en casa

Durante el programa en casa

13. Nutrición cardiosaludable
14. Hipertensión y corazón
15. Tabaco y corazón
16. Alcohol y corazón
17. Colesterol y corazón
18. Diabetes y corazón
19. Disfunción sexual y corazón
20. Continuar cuidando de mi corazón de forma integral
21. La importancia del tratamiento farmacológico
22. Dudas y debate sobre el tratamiento farmacològico
23. Cómo y cuando pedir ayuda
24. Merienda de despedida

ANNEX VIII – ATTENDANCE CONTROL

UNIDAD DE REHABILITACIÓN CARDÍACA

CONTROL DE ASISTENCIA

NOMBRE Y APELLIDOS:

Sesiones ejercicios		**1ª sesión del mes**	**2ª sesión del mes**	**3ª sesión del mes**	**4ª sesión del mes**	**5ª sesión del mes**	**6ª sesión del mes**	**7ª sesión del mes**	**8ª sesión del mes**
Mes 1	Fecha								
	Signatura								
Mes 2	Fecha								
	Signatura								
Mes 3	Fecha								
	Signatura								

Sessions educativas		**1a sesión del mes**	**2a sesión del mes**	**3a sesión del mes**	**4a sesión del mes**
Mes 1	Fecha				
	Signatura				
Mes 2	Fecha				
	Signatura				
Mes 3	Fecha				
	Signatura				
Mes 4	Fecha				
	Signatura				
Mes 5	Fecha				
	Signatura				
Mes 6	Fecha				
	Signatura				

Soporte psicológico		**1a sesión del mes**	**2a sesión del mes**	**3a sesión del mes**	**4a sesión del mes**
Mes 1	Fecha				
	Signatura				
Mes 2	Fecha				
	Signatura				
Mes 3	Fecha				
	Signatura				
Mes 4	Fecha				
	Signatura				
Mes 5	Fecha				
	Signatura				
Mes 6	Fecha				
	Signatura				

ANNEX IX – PROGRESSION CONTROL

UNIDAD DE REHABILITACIÓN CARDÍACA

CONTROL DE PROGRAMAS DE MARCHAS

NOMBRE Y APELLIDOS:

FREQUENCIA CARDIACA DE ENTRENAMIENTO:

ESCALA DE BORG OBJETIVO:

FECHA	KILOM.	TIEMPO	FQ	BORG	INCIDENCIAS

ANNEX X – THE BORG SCALE: RATE OF PERCEIVED EXERTION

UNIDAD DE REHABILITACIÓN CARDÍACA

ESCALA DE BORG: INDICE DE ESFUERZO PERCIBIDO

Indique que nivel de esfuerzo le parece más apropiado al ejercicio que ha realizado en ésta sesión. Y regístrelo regularmente en su hoja de control de marchas.

ESCALA DE BORG	**Descripción**
0	**Reposo total**. Inactivo.
1	**Esfuerzo muy suave**
2	**Suave**. Usado para calentamiento y estiramientos.
3	**Esfuerzo moderado**. Respiración y corazón acelerados.
4	**Algo duro**
5-6	**Duro**. Respiración intensa, difícil mantener una conversación
7-8	**Muy duro**
9	**Demasiado duro**. Imposible hablar.
10	**Esfuerzo máximo**. Imposible de mantener.

ANNEX XII- SF-36 QUESTIONNAIRE

1. En general, usted diría que su salud es:

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Excelente	Muy buena	Buena	Regular	Mala

2. ¿Cómo diría usted que es su salud actual, comparada con la de hace un año?:

Mucho mejor ahora que hace un año	Algo mejor ahora que hace un año	Más o menos igual que hace un año	Algo peor ahora que hace un año	Mucho peor ahora que hace un año
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

3. Las siguientes preguntas se refieren a actividades o cosas que usted podría hacer en un día normal. Su salud actual, ¿le limita para hacer esas actividades o cosas? Si es así, ¿cuánto?

	Sí, me limita mucho	Sí, me limita un poco	No, no me limita nada
a Esfuerzos intensos, tales como correr, levantar objetos pesados, o participar en deportes agotadores.	☐ 1	☐ 2	☐ 3
b Esfuerzos moderados, como mover una mesa, pasar la aspiradora, jugar a los bolos o caminar más de 1 hora.	☐ 1	☐ 2	☐ 3
c Coger o llevar la bolsa de la compra.	☐ 1	☐ 2	☐ 3
d Subir varios pisos por la escalera.	☐ 1	☐ 2	☐ 3
e Subir un sólo piso por la escalera.	☐ 1	☐ 2	☐ 3
f Agacharse o arrodillarse.	☐ 1	☐ 2	☐ 3
g Caminar un kilómetro o más	☐ 1	☐ 2	☐ 3
h Caminar varios centenares de metros.	☐ 1	☐ 2	☐ 3
i Caminar unos 100 metros.	☐ 1	☐ 2	☐ 3
j Bañarse o vestirse por sí mismo.	☐ 1	☐ 2	☐ 3

4. Durante las 4 últimas semanas, ¿con qué frecuencia ha tenido alguno de los siguientes problemas en su trabajo o en sus actividades cotidianas, a causa de su salud física?

	Siempre	Casi siempre	Algunas veces	Sólo alguna vez	Nunca
a ¿Tuvo que reducir el tiempo dedicado al trabajo o a sus actividades cotidianas?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b ¿Hizo menos de lo que hubiera querido hacer?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c ¿Tuvo que dejar de hacer algunas tareas en su trabajo o en sus actividades cotidianas?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d ¿Tuvo dificultad para hacer su trabajo o sus actividades cotidianas (por ejemplo, le costó más de lo normal)?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. Durante las 4 últimas semanas, ¿con qué frecuencia ha tenido alguno de los siguientes problemas en su trabajo o en sus actividades cotidianas, a causa de algún problema emocional (como estar triste, deprimido o nervioso)?

	Siempre	Casi siempre	Algunas veces	Sólo alguna vez	Nunca
a ¿Tuvo que reducir el tiempo dedicado al trabajo o a sus actividades cotidianas por algún problema emocional?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b ¿Hizo menos de lo que hubiera querido hacer por algún problema emocional?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c ¿Hizo su trabajo o sus actividades cotidianas menos cuidadosamente que de costumbre, por algún problema emocional?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. Durante las 4 últimas semanas, ¿hasta qué punto su salud física o los problemas emocionales han dificultado sus actividades sociales habituales con la familia, los amigos, los vecinos u otras personas?

Nada	Un poco	Regular	Bastante	Mucho
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. ¿Tuvo dolor en alguna parte del cuerpo durante las 4 últimas semanas?

No, ninguno	Sí, muy poco	Sí, un poco	Sí, moderado	Sí, mucho	Sí, muchísimo
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

8. Durante las 4 últimas semanas, ¿hasta qué punto el dolor le ha dificultado su trabajo habitual (incluido el trabajo fuera de casa y las tareas domésticas)?

Nada	Un poco	Regular	Bastante	Mucho
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

9. Las preguntas que siguen se refieren a cómo se ha sentido y cómo le han ido las cosas durante las 4 últimas semanas. En cada pregunta responda lo que se parezca más a cómo se ha sentido usted. Durante las últimas 4 semanas ¿con qué frecuencia...

	Siempre	Casi siempre	Algunas veces	Sólo alguna vez	Nunca
a se sintió lleno de vitalidad?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b estuvo muy nervioso?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c se sintió tan bajo de moral que nada podía animarle?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d se sintió calmado y tranquilo?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
e tuvo mucha energía?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
f se sintió desanimado y deprimido?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
g se sintió agotado?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

h se sintió feliz?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
i se sintió cansado?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

10. Durante las 4 últimas semanas, ¿con qué frecuencia la salud física o los problemas emocionales le han dificultado sus actividades sociales (como visitar a los amigos o familiares)?

Siempre	Casi siempre	Algunas veces	Sólo alguna vez	Nunca
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

11. Por favor diga si le parece CIERTA o FALSA cada una de las siguientes frases:

	Totalmente cierta	Bastante cierta	No lo sé	Bastante falsa	Totalmente falsa
a Creo que me pongo enfermo más facilmente que otras personas	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Estoy tan sano como cualquiera	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Creo que mi salud va a empeorar	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Mi salud es excelente	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Gracias por contestar a estas preguntas